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Food Inspection Accreditation

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Report Highlights:

On November 18, 2009 China notified "Qualification Certification Requirements for Food Inspection and Testing Agencies" to the WTO as G/SPS/N/CHN/123. Comments are due on January 17, 2010. This report contains an UNOFFICIAL translation of this draft measure.

Executive Summary:

On November 18, 2009 China notified "Qualification Certification Requirements for Food Inspection and Testing Agencies" to the WTO as G/SPS/N/CHN/123. Comments are due on January 17, 2010. The proposed date of adoption and entry into force is February 1, 2010.

China's WTO notification describes the regulation as, "According to the *Food Safety Law of the People's Republic of China*, this regulation specifies the requirements for the organization, inspection ability, quality control, staff, facilities and environment, apparatus and equipments, standard

substances that should be met by food inspection and testing agencies.”

Thanks go to the Embassy of Australia in the People’s Republic of China for assistance with this translation.

This report contains an UNOFFICIAL translation of this draft measure.

General Information:

BEGIN TRANSLATION

Qualification Certification Requirements for Food Inspection and Testing Agencies

(Draft for comments)

Chapter I General provisions

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| Article I | These accreditation requirements are formulated in accordance with “Food Safety Law of the People’s Republic of China” (hereinafter referred to as “Food Safety Law”) and its implementation rules to strengthen management on food inspection agencies. |
| Article II | These accreditation requirements apply to the accreditation of food inspection agency engaged in food inspection activities under the Food Safety Law. |
| Article III | These accreditation requirements prescribe the requirements for food inspection agencies in organization structure, inspection capacity, quality management, staff, facilities, environment, apparatuses and equipments, and standard materials. |
| Article IV | The food inspection agencies applying for accreditation should be able to ensure the integrity and impartiality of inspection activities and meet the requirements of “Laboratory Accreditation Criteria” and these accreditation requirements. |

Chapter II Organization

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| Article V | The food inspection agency should be an inspection agency established (registered) in accordance with laws or a relatively independent organization which can assume correspondent legal liabilities. |
| Article VI | The top management of a food inspection agency which is an independent legal entity shall be its legal representative; the top management of a food inspection agency which is not an independent legal entity shall be the legal representative of the corporate. |
| Article VII | The food inspection agency shall engage inspection staffs who are officially employed.
The inspection staff can only practice in one food inspection agency.
The food inspection agency must not hire staff that is forbidden to be engaged in food inspection by state laws and regulations. |
| Article VIII | The food inspection agency carrying out animal experiments shall obtain “Certificate for Environment and Facilities of Laboratory Animals” issued by Laboratory Animal Management Authority above the provincial level; the inspection agency which uses animals raised by the agency must have “Laboratory Animal Production License” and |

“Quality Certification for Laboratory Animals”.

Chapter III Inspection Capacity

- Article IX The food inspection agency shall have one or more of the following inspection capacities:
- (I) Capacity to conduct inspections on test items of foods of one or more categories prescribed in relevant food safety standards, including inspection of physical, chemical and all microbial items, additives and nutrition enhancers in foods.
 - (II) Capacity to conduct inspections on test items of food additives of one or more categories prescribed in relevant food safety standards, including inspection of physical, chemical and all microbial items.
 - (III) Capacity to conduct inspections on test items of food-related products (containers, packaging materials, etc) of one or more categories prescribed in relevant food safety standards, including inspection of physical, chemical and all microbial items
 - (IV) Capacity to conduct special inspections on test items of pollutants, pesticide residues, and residues of veterinary drugs prescribed in general or relevant food safety standards.
 - (V) Capacity to conduct the etiological identification for food poisoning (including chemical and biological poisoning reasons).
 - (VI) Capacity to conduct toxicological safety evaluation on “Risk Assessment” and administrative license of food safety.
 - (VII) Capacity to supply other inspection data and results to the government and society to facilitate the implementation of the “Food Safety Law”.

Chapter IV Quality management

- Article X Food inspection agencies shall set up and implement a quality management system tailored to the inspection activities in accordance with Work Rules for Food Inspection.
- Article XI Food inspection agencies shall formulate correspondent inspection accountability system, management system for the inspection data and emergency inspection plan for food safety incidents in accordance with “Food Safety Law”.
- Article XII Food inspection agencies entrusted by the government with supervision, sampling, and food safety risk monitoring and evaluation shall formulate correspondent work system.

Chapter V Staff

- Article XIII Food inspection agencies shall have inspection staff and technical managers tailored to the inspection activities conducted.
- Article XIV The inspection staff and technical managers should be familiar with “Food Safety Law” and relevant laws and regulations, relevant food safety standards, inspection methods and theory, inspection operation skills, standard operational procedures, quality control requirements, lab safety and protection knowledge, computation and data processing knowledge, etc.

- Article XV The inspection staff and technical managers should accept trainings on “Food Safety Law” and relevant laws and regulations and professional trainings and evaluations; they should also have certifications for the fulfillment of trainings and evaluations.
- Article XVI The inspection staff engaged in animal experiments should have “Certificates for Practitioners Engaged in Animal experiments”; the staff engaged in special inspection projects (radiation, gene inspection) should meet the requirements of relevant laws and regulations.
- Article XVII The staff engaged in food inspection activities in food inspection agencies with technical titles above the medium level (including medium) should be no less than 30%.
- Article XVIII The technical managers in food inspection agencies should have technical titles above the medium level (including medium) of relevant specialties and over three years’ of work experiences in food inspection.

Chapter VI Facilities and environment

- Article XIX Food inspection agencies should have fixed inspection sites and facilities and equipment for refrigerating and freezing, data processing and analyzing, and information transmission needed in food inspection activities.
- Article XX The infrastructure and work environment of the food inspection agencies should meet the requirements of ensuring the normal operation of inspection methods and apparatuses and equipment, the keeping of technical records, the preparation and storage of samples, the prevention of cross contamination and the protection of human health and environment.
The lab area should be separated from the non-lab area; The adjacent areas that exert influence on each other shall be segregated effectively; the area that needs to be controlled should be indicated clearly.
- Article XXI The Microbiology labs should be equipped with biological safety cabinets; the experiments involved with pathogens should be conducted in biosafety labs of the correspondent levels in accordance with “Biosafety Management Regulation of Laboratories for Micro-organisms” issued by the State Council.
- Article XXII The food inspection agencies carrying out animal experiments shall meet the following requirements:
- (I) There are environmental monitoring facilities for temperature, moisture, ventilation and light control;
 - (II) There are independent quarantine rooms for laboratory animals;
 - (III) There are disinfection and sterilization facilities tailored to the animal experiment project;
 - (IV) There are facilities for the collection and placement of animal waste and other wastes;
 - (V) There are necessary and independent spaces for the separated rearing of animals of different species and in different lab projects, the single-cage rearing and segregation of sick animals;
 - (VI) The food inspection agency conducting experiments involved with volatile or radioactive substances or micro-organisms should be equipped with special animal laboratories and correspondent protection measures (including ventilation and sewage system), which are completely separated from regular animal labs.

- Article XXIII Toxicology labs should be equipped with facilities for the storage and disposal of positive control materials in line with the environmental requirements. The labs used for in vitro toxicology inspection should have enough independent spaces to conduct genetic toxicity experiment of micro-organisms and cells separately; besides, they should meet the relevant national biosafety requirements.
- Article XXIV Food inspection agencies should have measures to prevent the damage, deterioration and loss of original data, records and reports. Where computer information technology or automatic equipment system are adopted to collect, process, analyze, record, report or store the inspection data and documents, measures should be taken to ensure the safety and completeness and the conformity to “Work Rules for Food Inspection”.

Chapter VII Apparatuses, equipment and standard materials

- Article XXV Food inspection agencies should be equipped with necessary apparatuses and equipment, pre-treatment devices for samples, and standard materials (reference materials) or standard bacteria (viruses).
- Article XXVI The apparatuses and equipment (including software) and standard materials (reference materials) or standard bacteria (viruses) of food inspection agencies are managed by designated staff to meet the traceability needs.

Chapter VIII Supplementary provisions

- Article XXVII These accreditation requirements are subject to the interpretation of the Ministry of Health of the People’s Republic of China.
- Article XXVIII These accreditation requirements come into force as of the release date.